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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,596	03/18/2004	Michael Lange	905.020US2	9548

7590 03/29/2007

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EXAMINER	
CHANG, CHING	
ART UNIT	PAPER NUMBER
3748	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,596	LANGE ET AL.	
	Examiner	Art Unit	
	Ching Chang	3748	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/08/2007 has been entered. Claims 1-16 are cancelled as requested.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. ***Claims 17-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

More specifically, " the sheath " in lines 2-3, 7, and 12 of claim 17, " the side port assembly " in lines 2-3 of claims 18-19, " the sheath " in line 2 of claim 22, " the sheath " in line 3 of claim 26, " the sheath coupling member " in line 3 of claim 26, " the sheath " in line 3 of claim 27, the sheath " in line 2 of claim 29, and " the sheath coupling member " in line 2 of claim 34 are lacking of antecedent basis, thus render the claimed subject matter in claims 17-34 indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. ***Claims 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Mooney et al. (US Patent 6,827,710).***

Mooney discloses a method (See Figs. 1-53) comprising: providing an introducer (10, 110, 400, 500, 600, 620, 650, etc.) including a sheath, a side port, and a side port assembly releasably coupled with the sheath, the sheath further including a side port valve, the side port assembly having a coupled position; uncoupling the side port assembly from the coupled position; and sealing the side port of the introducer (through 70, 154, see Figs. 21-22, Figs. 26-27, etc.) with the side port valve after the side port assembly is removed from the coupled position, wherein uncoupling the side port assembly includes uncoupling a snap fit coupling, wherein uncoupling the side port

assembly includes uncoupling a threaded coupling, further comprising coupling the side port assembly to the coupled position and opening the side port valve with a valve opening component associated with a side port coupling member, further comprising permitting passage of fluids through the valve opening component, further comprising coupling a cap with the sheath after uncoupling the side port assembly.

6. ***Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck (US Patent 6,083,207).***

Heck discloses an introducing apparatus (See Fig.1) comprising: an elongate tubular sheath (20) having an external diameter, the elongate tubular sheath having a bore including an internal diameter sized to receive a dilator (300) there through, the elongate tubular sheath comprising a separable sheath; a side member (including 120) disposed on the elongate tubular sheath between a sheath proximal end and a sheath distal end; the elongate tubular sheath extending from a distal end to a proximal end; at least one tab (204, 212) extending away from a longitudinal axis of the sheath, the at least one tab disposed between the side member and the elongate tubular sheath; and a releasable side port assembly (16, 122, 124) coupled with the sheath with a coupling (18), and the releasable side port assembly includes one or more features (100) allowing for the releasable side port assembly to be released from the sheath without damage or separation of the sheath or the releaseble side port assembly; wherein the releasable side port assembly is coupled with the separable sheath with a snap-fit connection (102).

7. ***Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Heck (US Patent 6,083,207).***

Heck discloses an introducer apparatus (See Fig. 1) comprising: an elongate tubular sheath (20) including a sheath member (including 120), the sheath extending from a proximal portion to a distal portion, the sheath member disposed on the elongate tubular sheath; a side port assembly (16, 122, 124) including a side port coupling member (18), the side port coupling member releasably coupled with the sheath member; and the side port assembly having a coupled position and an uncoupled position.

8. ***Claims 17-22, 25, 26-29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US Patent 5,755,693) in view of Scarfone et al. (US Patent 5,300,046), and further in view of West et al. (US Patent 6,322,541).***

Walker discloses an introducing apparatus, comprising: an elongate tubular sheath (18) having an external diameter, the elongate sheath having a bore (24) including an internal diameter sized to receive a dilator (12; or the like) there through, the elongate tubular sheath comprising a separable sheath (through 56, 58, and 18); the sheath extending from a distal end to a proximal end; at least one tab (56, 58) extending away from a longitudinal axis of the sheath; and a movable valve assembly (64, 64a) movably coupled relative to the at least one tab, the moveable valve assembly adapted to move from a first position (See Fig. 12 and 15) to a second position (other than the first position, along 28), in the first position the movable valve assembly disposed

through the longitudinal axis of the sheath, in the second position the movable valve assembly disposed away from the longitudinal axis of the sheath.

Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to Scarfone on the other hand, teaches that it is conventional in the sheath catheter assembly art, to utilize a side port assembly (See Figs. 1-2) attached to sheath catheter assembly (102), including a passage (126) permitting introduction of fluids through the side port assembly, and a stop cock assembly (128).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port assembly attached to the sheath as taught by Scarfone in the Walker device, since the use thereof would provide an improved sheath introducer, with additional fluid flowing through as needed.

The modified Walker device, however, fails to disclose the side port assembly being releasable coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable snap-fit connection or thread-connection coupling between a hub (22) and a cap (24)(see Col. 2, line 56 through Col. 3, line 8), with a sealing valve (26) inbetween them.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a releasable coupling of a snap-fit connection or thread-connection between the sheath and the side port assembly, as taught by West, in the modified Walker device, since the use thereof would provide an improved

introducer, with an attachable side port for a flush or injection of other fluid in a vascular access system.

9. ***Claims 23-24, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone et al., and further in view of West et al. (as applied to claims 22, and 26), and further in view of Trinder (US Patent 2,493,326).***

The modified Walker device discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Walker device, since the use thereof would provide an improved introducer, with a better control on the fluid flowing through.

10. ***Claims 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone et al., and further in view of West et al. (as applied to claims 26), and further in view of Dressel (US Patent 5,120,420).***

The modified Walker device discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified Walker device, since the use thereof would provide an improved device to prevent fluid leak from an introducer.

11. ***Claims 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Roth et al. (US Patent 5,405,334).***

Roth discloses a method (See Figs. 1-16) comprising: providing an introducer (10, 10b, 10c, etc.) including a sheath, a side port, and a side port assembly releasably coupled with the sheath, the sheath further including a side port valve, the side port assembly having a coupled position; uncoupling the side port assembly from the coupled position; and sealing the side port of the introducer (through 40, 78, 108, etc.) with the side port valve after the side port assembly is removed from the coupled position, wherein uncoupling the side port assembly includes uncoupling a snap fit coupling, wherein uncoupling the side port assembly includes uncoupling a threaded coupling, further comprising coupling the side port assembly to the coupled position and opening the side port valve with a valve opening component associated with a side port coupling member, further comprising permitting passage of fluids through the valve

opening component, further comprising coupling a cap with the sheath after uncoupling the side port assembly.

12. ***Claims 17-20, 22, 25, 26-29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,312,355) in view of West et al. (US Patent 6,322,541).***

Lee discloses an introducing apparatus, comprising: an elongate tubular sheath (12) having an external diameter, the elongate sheath having a bore (24) including an internal diameter sized to receive a dilator (28) there through, the elongate tubular sheath comprising a separable sheath; the sheath extending from a distal end to a proximal end; at least one tab (38, 40) extending away from a longitudinal axis of the sheath.

Lee further discloses a side port assembly (18, 20) being coupled with the sheath.

The Lee device, however, fails to disclose the side port assembly being releasable coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable snap-fit connection or thread-connection coupling between a hub (22) and a cap (24)(see Col. 2, line 56 through Col. 3, line 8), with a sealing valve (26) inbetween them.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a releasable coupling of a snap-fit connection or thread-connection between the sheath and the side port assembly, as taught by West,

in the Lee device, since the use thereof would provide an improved introducer, with an attachable side port for a flush or injection of other fluid in a vascular access system.

13. ***Claims 23-24, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of West et al. (as applied to claims 22, and 26), and further in view of Trinder (US Patent 2,493,326).***

The modified Lee device discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Lee device, since the use thereof would provide an improved introducer, with a better control on the fluid flowing through.

14. ***Claims 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of West et al. (as applied to claims 26), and further in view of Dressel (US Patent 5,120,420).***

The modified Lee device discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified device, since the use thereof would provide an improved device to prevent fluid leak from an introducer.

15. ***Claims 26-40 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Dormandy et al. (US Patent 4,819,637).***

Dormandy discloses an introducer apparatus, and a method (See Figs. 1-2) of use it, comprising: providing an introducer (10) including a sheath (15), a side port (including 21), and a releasable side port assembly releasably (including 23) coupled with the sheath, the sheath further including a side port valve, the side port assembly having a coupled position; uncoupling the side port assembly from the coupled position; and sealing the side port of the introducer with the side port valve after the side port assembly is removed from the coupled position, wherein uncoupling the side port assembly includes uncoupling a snap fit coupling, wherein uncoupling the side port assembly includes uncoupling a threaded coupling, further comprising coupling the side port assembly to the coupled position and opening the side port valve with a valve opening component associated with a side port coupling member, further comprising

permitting passage of fluids through the valve opening component, further comprising coupling a cap with the sheath after uncoupling the side port assembly.

16. ***Claims 17, 19-20, 26, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Williams et al. (US Patent 5,871,530).***

Williams discloses an introducer apparatus, and a method (See Figs. 1-10) of use it, comprising: providing an introducer (10, 100) including an elongate tubular sheath (30, 110), a side port (connected to 106), and a releasable side port assembly releasably (including 108, 114) coupled with the sheath, the sheath further including a side port valve, the side port assembly having a coupled position; uncoupling the side port assembly from the coupled position; and sealing the side port of the introducer with the side port valve after the side port assembly is removed from the coupled position, wherein uncoupling the side port assembly includes uncoupling a threaded coupling; wherein the side port assembly further includes a stop cock assembly.

Response to Arguments

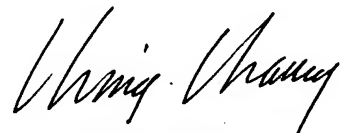
17. Applicant's arguments with respect to claims 17-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (571)272-4857. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (571)272-4859. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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